

# The High Cost of Noncompliance in the US Pharmaceutical Industry

By Patricia Santos-Serrão

Today's life sciences companies face a deepening morass of compliance challenges as regulations continue to multiply. Indeed, the pharmaceutical industry is rightly regarded as one of the most highly regulated in the world. Staying current on new legislation and reinterpretation of existing regulations issued by the Food and Drug Administration (FDA) and its international counterparts requires the constant vigilance of even the most detail-oriented regulatory affairs professional.

While the compliance needs of life sciences companies vary by niche, maturity and market clout, they share a universal need to prove to regulatory bodies and the public at large that they have done everything possible to comply with not only the letter of the law, but also its spirit. In the midst of one of the most litigious eras in history, life sciences companies must consistently and scrupulously maintain, update and revisit their compliance processes and procedures or suffer unacceptable consequences.

In addition to FDA, life sciences companies are subject to the same regulatory bodies and scrutiny facing other industries. The most significant of these are the Securities and Exchange Commission (SEC) and the Environmental Protection Agency (EPA). Warnings and fines from SEC and EPA do not impact life sciences companies in the same way that drug recalls do, but they create the image of an ill- or loosely run company simply waiting for the next scandal to hit.

Although the current US administration has maintained a less-active approach to regulation, it has not turned a blind eye to egregious violations of accepted environmental and business practices. The headlines in any major business publication show how many life sciences companies run afoul of these regulatory bodies every year.

## EPA and the Pharmaceutical Industry

According to EPA's mission statement, the agency is tasked with protecting human health and the environment to ensure a cleaner, healthier environment for the American people. To achieve its goals, EPA develops and enforces regulations, performs environmental research and, as necessary, audits various companies to secure adherence to such regulations. In the case of deviations from acceptable environmental stewardship, the agency issues warn-

ings and fines for lack of compliance with its edicts. As operators of numerous manufacturing and packaging plants, pharmaceutical companies often come under EPA's auspices.

In a perfect world, life sciences companies would be able to find a cure for all diseases—and do so with no negative impact to the environment. Despite our best efforts, however, this is not a perfect world and even companies with the best of intentions can fall short of environmental standards.

A look at recent history shows that one company reached a settlement with the EPA after it was found to be non-compliant with leak detection and repair requirements for hazardous air pollutants in its manufacturing plant. Another company decided to abandon a project and, instead of disposing of its materials properly, was deemed to have flushed them down a drain, resulting in discharge of chemicals to a local water treatment plant. A downstream treatment plant fed a local creek where the pollutants killed more than 1,000 fish. These two incidents alone cost the two companies close to a combined \$80,000 in fines and penalties, not to mention the cost of cleaning up and rectifying the issues that caused the violations or the damage to their reputations.

On a positive note, many companies are in tune with public sentiment toward greater environmental oversight and have made significant improvements in recent years regarding environmental events. They have proactively disclosed information on how they intend to demonstrate corporate responsibility and their environmentally sound policies by publishing sustainability reports and corporate environmental performance reports. Some companies also conduct internal environmental, health and safety (EHS) audits, as well as audits of contract manufacturing partners.

In many cases, businesses have led regulatory reform, realizing the goodwill engendered by such actions can positively impact the bottom line. Regardless of the impetus for regulatory change, maintaining up-to-date rules interpretations is the bedrock of sound compliance policy.

## SEC: Not Just the Financial Industry's Problem

Many recent reforms in corporate governance resulted from large, well-publicized financial frauds



and scandals involving companies such as Enron, Tyco and MCI. In response to those frauds, Congress overwhelmingly passed the *Sarbanes-Oxley Act of 2002 (SOX)*. SEC adopted many new rules and the major stock markets changed their standards for governing public companies. Because of its expensive and time-consuming reporting requirements, *SOX* has come under fire in the past year for restricting the allure of the US capital markets, but the main components of the act are unlikely to change in the near future.

Most well-run public companies are very aware of their *SOX* responsibilities. Major pharmaceutical companies are no exception to that rule, but they sometimes stumble. Recently, a major pharmaceutical company agreed to pay a \$100 million civil fine and \$50 million in other fines levied by SEC in response to accounting violations. The agency said the company conducted a cover-up by selling massive quantities of drugs to wholesalers and then improperly booking the revenue from \$1.5 billion of those sales.

In another instance, a pharmaceutical company and three of its top executives were fined a combined \$1.5 million for allegedly making misleading public statements concerning the status of a new drug application. Not surprisingly, these comments positively impacted stock prices, which later plummeted when news of the drug's rejection was released. These are just a few examples of the importance of the pharmaceutical industry's adherence to financial disclosure regulations.

## Managing Compliance

The various compliance demands from FDA, EPA, SEC and every acronym regulating the pharmaceutical industry can seem overwhelming at times. But regardless of the regulations in question, compliance teams should always fall back on the tried and true practices learned by dealing with the very familiar FDA.

Compliance has the same meaning, regardless of the agency. Companies must adhere or conform to rules and regulations and show evidence of doing so, and put measures into place that ensure compliance is achieved. A well-run company must be able to audit itself and, at any given moment, analyze its compliance status to show not only that employees have understood what should be done, but also that the who, what, where, when and why of actions taken are recorded in a non-editable fashion. In any language and any country, that is the core of compliance.

The basics of compliance are well-known, regardless of the agencies involved. Most people

agree that highly effective companies utilize seven habits to form a closed loop of compliance. In brief, these seven habits help companies (1) track and interpret regulations, and (2) document policies and procedures. After embedding these first two habits into the corporate culture, the information must reach the affected parties through (3) effective training programs. Once policies have been communicated, what follows is (4) monitoring for deviations, (5) aggressively auditing and investigating anomalies and, where necessary, (6) managing exceptions and deviations. This final puzzle piece requires (7) implementing and measuring change.

To automate the compliance process and reduce the overall drain of resources allocated to compliance initiatives, many companies are currently evaluating compliance management systems or planning to do so in the near future. During the review process, evaluators should note that the underlying structure for compliance—the seven habits—is consistent, regardless of the regulatory body involved. Therefore, the compliance management system in question should be able to span the enterprise. Each functional area, such as legal, finance, human resources, clinical and manufacturing, should be able to use the system to achieve its compliance objectives. Configurable management systems that allow all functional areas to meet their compliance requirements with the same core products can save both time and money, both in implementation and the repercussions of being noncompliant.

In highly regulated industries like life sciences, compliance is an ongoing concern and too important to monitor and administer in an ad hoc manner. Companies merge, laws are written, agencies reinterpret – and therefore, compliance officers must be proactive in managing risk. Regulations need to be identified, interpretation agreed upon, information dispensed and procedures monitored. Issues need to be addressed as they arise and be fed into the process improvement element of regulatory interpretations.

The loop needs to be closed and the process repeated on an ongoing basis. A closed-loop risk model promotes a sustainable and cost-effective program, which is the only way to accurately capture and manage compliance risk and remediate regulatory violations across the enterprise.

Compliance officers who ignore the seven habits of closed-loop compliance do so at incredible risk.

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